**Citation:**

Ellison RC, Capper AL, Stephenson WP, Goldberg RJ, Hosmer DW Jr, Humphrey KF, Ockene JK, Gamble WJ, Witschi JC, Stare FJ. Effects on blood pressure of a decrease in sodium use in institutional food preparation: The Exeter-Andover Project. *J Clin Epidemiol.* 1989; 42 (3): 201-208.

**PubMed ID:** 2709080

**Study Design:**

Non-randomized, concurrently controlled, longitudinal investigation, with the applications of the intervention in each of two boarding high schools in alternate school years.

**Class:**

C - Click here for explanation of classification scheme.

**Research Design and Implementation Rating:**

POSITIVE: See Research Design and Implementation Criteria Checklist below.

**Research Purpose:**

To determine whether modifications in institutional food purchasing and preparation practices designed to reduce sodium content of dining hall foods are effective in producing blood pressure (BP) changes among adolescents.

**Inclusion Criteria:**

- While the entire student body was exposed to the dietary changes, for logistic reasons, intervention effects were monitored only among students (both boarders and non-boarders) enrolled in basic courses in science at Phillips Exeter Academy, Exeter, NH and Phillips Academy, Andover, MA
- Since "non-boarding" students usually consumed more than a single meal in the dining halls each day, they were included in the project.

**Exclusion Criteria:**

Not reported.

**Description of Study Protocol:**

**Recruitment**

Participants were high school students at Phillips Exeter Academy, Exeter, NH and Phillips Academy, Andover, MA.

**Design**

- Non-randomized, concurrently controlled, longitudinal investigation
- Comparisons were made between students at the school in which there were changes in food preparation (intervention school) and the students at the school where there were no changes in food preparation (control school)
- During the first year, both schools began with a five-week period in which the regular diet was prepared and the Exeter school received the intervention diet for that year
- Upon beginning the second year, the usual diet was given for five weeks at the start and the Andover school was given the intervention diet.

**Blinding Used**

- Students were aware that during intervention years, the sodium content of the food provided was decreased
- Students were blinded to self-measured BP from automatic device, because results were saved directly to floppy disk and not shown to students
- Analysis of food diaries and recipes was performed by trained dieticians, but the report does not state whether or not these dieticians were blinded to the intervention group.

**Intervention**

- All participants regardless of group assignment. Since the aim of the project was to determine the effects of a "passive" intervention involving changes in food purchasing and preparation, students were not instructed to modify their eating practices or avoid salty foods. The only active education about salt modification was the placement on the tables of a listing of the sodium content of cereals available in the dining halls. Otherwise, students were advised to eat as usual, and salt shakers were left on the tables. As much as possible, students at the two schools received similar information about the study and encouragement to comply with monitoring procedures, regardless of whether the school was in the intervention or control year
- Intervention year: Food purchasing practices were modified so that certain meat products, cheeses, potato chips and other foods with a lower sodium content were obtained. Cooks at each institution prepared foods with less added salt, utilizing non-sodium-containing spices and other flavorings
- Control year: No changes in food preparation.

**Statistical Analysis**

- Data from an individual student were included in the analysis if he/she had at least one set of BP measurements during both the baseline and follow-up periods
- The primary methods of statistical analysis were one and two sample T-tests
- Analysis of covariance was used to obtain adjusted effects of the intervention
- Hypothesis tests and other inferences for changes in nutrient intake required calculation of the variance of the ratio of two means based on different sample sizes; this was accomplished through standard Taylor series expansion of the ratio and estimation of the parameters using all available data.

**Data Collection Summary:**

**Timing of Measurements**

- Students were asked to complete 24-hour food diaries on one assigned weekday or weekend

day during each week during the first six weeks of school, during two weeks in winter and during four weeks in spring
- For certain basic courses in biology and chemistry at the two schools during the two years, each student was asked to measure his/her own BP each week during the usual laboratory period.

**Dependant variables**

- Blood pressure: Each student measured his/her own blood pressure each week using an automatic device, which connected through an interface to an Apple II computer
- On each occasion, three measurements of systolic (SBP) and diastolic blood pressure (DBP) heart rate, ID number of the student and the date and time of day were recorded on a floppy disk. For each set of three BPs recorded at a time, the average of the second and third was taken as the BP for that session
- The main outcome measures were the average changes in SBP and DBP of subjects between the beginning of the school year and the end of the school year, comparing students in the intervention school with those in the control school
- Each of the eight BP devices used in the study were sent to the factory for cleaning, testing and recalibration just prior to each school year. After maintenance procedures, the machines were distributed randomly to the two schools for each year of the study. (By chance, two of the three machines used by Andover during its intervention year had been used at Exeter during its intervention year.) Static calibration of each machine with a mercury manometer was done at the beginning of each school year and at approximately four-week intervals thereafter
- The baseline BP for an individual was taken as the average of all recordings obtained during four weeks near the beginning of the school year, when both schools were having food prepared using “usual” methods
- The follow-up BP consisted of the average of each student’s pressure obtained during a six-week period near the end of the school year, in April and early May.

**Independent Variables**

- Nutrient intake: All foods ingested were recorded and described, whether they were obtained from the dining hall, school snack bars or from outside the school (the latter furnishing approximately 28% if calories and sodium)
- Salt added to foods at the table was indicated on the diaries and the amount estimated, using a validated scale
- Analysis of food diaries and recipes was performed by trained dieticians using the “Food Finder” program at the Center for Clinical Computing, Beth Israel Hospital, Boston
- Sodium values calculated from recipes in both regular and reduced-sodium periods were added to the computerized nutrient data bank, as were values obtained by chemical analysis for commercially prepared reduced-sodium foods.

**Control variables**

Information given to students was the same for both control and intervention years and both groups were instructed not to modify their eating practices or avoid salty food.

**Description of Actual Data Sample:**

- *Initial N:*

- 400 students in the intervention group
- 415 students in the control group

- *Attrition (final N):*
  - Only 309 students provided data from the intervention group, and 341 students provided data from the control group
  - The majority of students not furnishing data for the analysis did not take the science course for the spring term, when the follow-up occurred
  - There were no significant (NS) differences in baseline BPs between those who withdrew and those remaining in the study.

| | Males | | Females | |
|---|---|---|---|---|
| | **Control N=193** | **Intervention N=152** | **Control N=148** | **Intervention N=157** |
| **Age (years)** | 15.1±0.9 | 15.2±0.8 | 14.9±0.7 | 14.9±0.6 |
| **Height (inches)** | 68.4±3.5 | 68.5±3.0 | 64.8±2.7 | 64.5±2.6 |
| **Weight (pounds)** | 142.7±25.8 | 141.2±22.1 | 124.7±16.9 | 123.7±18.0 |
| **Race (% White)** | 78 | 80 | 75 | 74 |
| **% boarders** | 81 | 81 | 84 | 76 |

Baseline demographic data, by age and intervention status (mean±SD)

| | Males | | | Females | | |
|---|---|---|---|---|---|---|
| | **Control N=193** | **Intervention N=152** | **P-value** | **Control N=148** | **Intervention N=157** | **P-value** |
| **SBP (mmHg)** | 109.3±8.3 | 111.9±8.4 | 0.009 | 101.7±7.6 | 105.8±8.1 | <0.001 |
| **DBP (mmHg)** | 62.0±6.6 | 65.8±6.5 | <0.001 | 61.7±7.0 | 66.1±6.4 | <0.001 |
| **HR (bpm)** | 72.2±9.4 | 73.4±10.2 | 0.3 | 76.0±10.6 | 76.2±12.6 | 0.9 |

Baseline physiologic data, by age and intervention status (mean±SD)

- Although all students were normotensive, higher SBP and DBP were present among students in the intervention group at baseline. These differences could not be explained by differences in height, weight or any other factors measured and are attributed to small differences in BP devices which could not be detected by the calibrations with mercury manometers.
- *Location:* Exeter, NH and Andover, MA (New England).

**Summary of Results:**

| Males: Baseline and Follow-up Dietary Data (mean±SD) | | |
|---|---|---|
| | **Control Difference (%)** | **Intervention Difference (%)** |
| **Calories** | -203 (-7%) | -188 |
| **Na (mEq)** | -4.8 (-3%) | -39.0 |
| **Na/kcal** | +1.5 (+3%) | -9.7 |
| **K (mEq)** | +1.0 (+1.0%) | +1.1 |
| **Na/K** | -0.1 (-5%) | -0.5 |
| **Females: Baseline and Follow-up Dietary Data (mean±SD)** | | |
| | **Control Difference (%)** | **Intervention Difference (%)** |
| **Calories** | -332 (-16%) | -248 (-12%) |
| **Na (mEq)** | -16.8 (-15%) | -28.0 (-25%) |
| **Na/kcal** | +1.2 (+2%) | -8.2 (-15%) |
| **K (mEq)** | -4.6 (-7%) | -1.2 (-2%) |
| **Na/K** | -0.2 (-10%) | -0.4 (-21%) |
| **Mean Changes in Blood Pressure (mmHg) Between Baseline and Follow-up** | | |
| | **Control Difference (95% CI)** | **Intervention Difference (95%CI)** |
| **Systolic** | -0.94 (-2.7, +0.8) | -2.55 (-4.3, -0.8) |
| **Diastolic** | -1.19 (-2.6, +0.2) | -2.54 (-4.0, -1.1) |

**Other Key Findings**

- There were NS differences between the control and intervention groups for any baseline demographic data
- Although all students were normotensive, higher SBP and DBP were present among students in the intervention group at baseline
- Changes in sodium measures suggest that the intervention resulted in a mean decrease in sodium intake of approximately 15-20%
- There were no differences between control and intervention groups for changes in height of weight during the intervention year. Overall, males increased their height by 0.7 in and their weight by 6.8 pounds; for females, the increases were 0.2 in for height and 4.2 pounds for weight
- For both control and intervention years, the data indicate an initial increase in BP, usually extending at least until the Christmas vacation. Thereafter, BPs returned to or slightly above baseline during the intervention years. Utilizing BP data throughout the school year (not just during the baseline and follow-up periods), regression analysis adjusting for sex and baseline pressures estimates the average effect of the intervention to be -0.39mmHg per month (P=0.01) for SBP and -0.44 mmHg per month (P<0.001) for DBP
- During the control years, BP increased slightly for both genders
- During the intervention years, SBP among males remained unchanged, while decreases occurred in DBP among males and in both SBP and DBP among females
- Examination of potential confounding of effect by baseline or changed in height, weight and body mass index, as well as race, age, boarding status, sex and baseline BP was carried out.

Only sex and baseline BP were found to demonstrate confounding, with a larger effect seen among females and among students with higher baseline BPs.

**Author Conclusion:**

- During adolescence, a modest decrease in sodium intake over a period of approximately six months produced a small, but significant difference in BP between the intervention and control groups
- Sodium reduction not having an immediate effect on BP may explain why some earlier studies of shorter duration did not show an effect
- Changes in food purchasing and preparation practices in two boarding high schools led to an estimated 15-20% decrease in total sodium intake on the part of students, taking into account salt added at table, snack foods and other food products obtained outside of the schools' dining halls
- This dietary change was effected by food service personnel without attempts to alter the eating practices of the students
- The food modifications were very acceptable to students and faculty
- Although the changes in sodium intake were modest, they were sufficient to have significant effect on BP.

***Reviewer Comments:***

- *Inclusion and exclusion criteria were not specified. The authors just stated that they included students from the two schools, but did not specify any disease states or if they excluded any students. The reader is left with questions of whether any of the students had any concurrent illnesses that were not mentioned and may have affected BP*
- *The population studied is not representative of the entire adolescent population, because the students have meals provided to them by the boarding school. Even though the study showed that sodium reductions were able to reduce BP, this effect may not be reproducible in a free-living population who are responsible for preparing their own meals*
- *As this was not a randomized controlled trial, it is possible that the two schools may not have comparable populations and that this would confound results. The authors justify pooling the control years of both schools because of similar baseline data, but there may be other confounding factors not identified*
- *The first year at the Exeter school was an intervention year, followed by a control year. There is potential for carryover effect in this population because the cooks might have become accustomed to adding less salt into the food prepared, therefore providing less sodium than the control year at the Andover school. Also, it is possible that students may be less likely to salt their own food following a low sodium year because they have become accustomed to the taste*
- *Although students were not blinded to their treatment group, the measurement of BP was blinded due to the use of an automatic device and the sending of data to floppy disk without the student knowing their readings*
- *Physical activity and exercise could contribute to decrease BP but was not accounted for*
- *Participants in all groups had decreases in caloric intake between baseline and follow-up. Although there was no effect of body weight on BPs, lower overall caloric intake may have influenced resultant BPs.*

*Research Design and Implementation Criteria Checklist: Primary Research*

## Relevance Questions

| | | |
|---|---|---|
| 1. | Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies) | Yes |
| 2. | Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about? | Yes |
| 3. | Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice? | Yes |
| 4. | Is the intervention or procedure feasible? (NA for some epidemiological studies) | Yes |

## Validity Questions

| | | |
|---|---|---|
| **1.** | **Was the research question clearly stated?** | Yes |
| 1.1. | Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified? | Yes |
| 1.2. | Was (were) the outcome(s) [dependent variable(s)] clearly indicated? | Yes |
| 1.3. | Were the target population and setting specified? | Yes |
| **2.** | **Was the selection of study subjects/patients free from bias?** | Yes |
| 2.1. | Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study? | Yes |
| 2.2. | Were criteria applied equally to all study groups? | Yes |
| 2.3. | Were health, demographics, and other characteristics of subjects described? | Yes |
| 2.4. | Were the subjects/patients a representative sample of the relevant population? | Yes |
| **3.** | **Were study groups comparable?** | Yes |
| 3.1. | Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT) | ??? |
| 3.2. | Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline? | Yes |
| 3.3. | Were concurrent controls used? (Concurrent preferred over historical controls.) | Yes |

| | | |
|---|---|---|
| 3.4. | If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis? | N/A |
| 3.5. | If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.) | N/A |
| 3.6. | If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")? | N/A |
| **4.** | **Was method of handling withdrawals described?** | Yes |
| 4.1. | Were follow-up methods described and the same for all groups? | Yes |
| 4.2. | Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.) | Yes |
| 4.3. | Were all enrolled subjects/patients (in the original sample) accounted for? | Yes |
| 4.4. | Were reasons for withdrawals similar across groups? | Yes |
| 4.5. | If diagnostic test, was decision to perform reference test not dependent on results of test under study? | N/A |
| **5.** | **Was blinding used to prevent introduction of bias?** | Yes |
| 5.1. | In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate? | Yes |
| 5.2. | Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.) | Yes |
| 5.3. | In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded? | N/A |
| 5.4. | In case control study, was case definition explicit and case ascertainment not influenced by exposure status? | N/A |
| 5.5. | In diagnostic study, were test results blinded to patient history and other test results? | N/A |
| **6.** | **Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?** | Yes |
| 6.1. | In RCT or other intervention trial, were protocols described for all regimens studied? | Yes |
| 6.2. | In observational study, were interventions, study settings, and clinicians/provider described? | N/A |

| | | |
|---|---|---|
| 6.3. | Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect? | Yes |
| 6.4. | Was the amount of exposure and, if relevant, subject/patient compliance measured? | Yes |
| 6.5. | Were co-interventions (e.g., ancillary treatments, other therapies) described? | Yes |
| 6.6. | Were extra or unplanned treatments described? | ??? |
| 6.7. | Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups? | Yes |
| 6.8. | In diagnostic study, were details of test administration and replication sufficient? | N/A |
| **7.** | **Were outcomes clearly defined and the measurements valid and reliable?** | Yes |
| 7.1. | Were primary and secondary endpoints described and relevant to the question? | Yes |
| 7.2. | Were nutrition measures appropriate to question and outcomes of concern? | Yes |
| 7.3. | Was the period of follow-up long enough for important outcome(s) to occur? | Yes |
| 7.4. | Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures? | Yes |
| 7.5. | Was the measurement of effect at an appropriate level of precision? | Yes |
| 7.6. | Were other factors accounted for (measured) that could affect outcomes? | Yes |
| 7.7. | Were the measurements conducted consistently across groups? | Yes |
| **8.** | **Was the statistical analysis appropriate for the study design and type of outcome indicators?** | Yes |
| 8.1. | Were statistical analyses adequately described and the results reported appropriately? | Yes |
| 8.2. | Were correct statistical tests used and assumptions of test not violated? | Yes |
| 8.3. | Were statistics reported with levels of significance and/or confidence intervals? | Yes |
| 8.4. | Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)? | Yes |
| 8.5. | Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)? | Yes |
| 8.6. | Was clinical significance as well as statistical significance reported? | ??? |

| | | |
|---|---|---|
| 8.7. | If negative findings, was a power calculation reported to address type 2 error? | N/A |
| **9.** | **Are conclusions supported by results with biases and limitations taken into consideration?** | Yes |
| 9.1. | Is there a discussion of findings? | Yes |
| 9.2. | Are biases and study limitations identified and discussed? | Yes |
| **10.** | **Is bias due to study's funding or sponsorship unlikely?** | Yes |
| 10.1. | Were sources of funding and investigators' affiliations described? | Yes |
| 10.2. | Was the study free from apparent conflict of interest? | Yes |